

**UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF NEW YORK**

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SIMIN KARIMIAN, Individually and on behalf :  
of all others similarly situated,  
Plaintiff, :  
  
vs. : Case No. 1:18-cv-07410-LDH-SMG  
ALKERMES PUBLIC LIMITED COMPANY, :  
RICHARD F. POPS, and JAMES M. FRATES, :  
Defendants. :  
  
:  
----- X  
BONNIE McDERMOTT, Individually and on :  
behalf of all others similarly situated,  
Plaintiff, :  
  
vs. : Case No. 1:19-cv-00624-LDH-SMG  
ALKERMES PUBLIC LIMITED COMPANY, :  
RICHARD F. POPS, and JAMES M. FRATES, :  
Defendants. :  
  
:  
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**MEMORANDUM OF LAW IN SUPPORT OF MOTION OF MIDWEST OPERATING  
ENGINEERS PENSION TRUST FUND FOR APPOINTMENT AS LEAD PLAINTIFF,  
APPOINTMENT OF LEAD COUNSEL, AND CONSOLIDATION OF  
RELATED ACTIONS**

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## I. INTRODUCTION

Pursuant to Section 21D(a)(3)(B) of the Securities Exchange Act of 1934 (the “Exchange Act”), as amended by the Private Securities Litigation Reform Act of 1995 (“PSLRA”), at 15 U.S.C. § 78u-4, and for the reasons set forth below, Midwest Operating Engineers Pension Trust Fund (“Midwest Operating Engineers” or “Movant”) respectfully moves this Court for an Order appointing Midwest Operating Engineers as Lead Plaintiff on behalf of itself and all others similarly situated who purchased Alkermes Public Limited Company (“Alkermes” or the “Company”) common stock between February 17, 2017 and November 1, 2018, inclusive (the “Class Period”). Midwest Operating Engineers also seeks appointment of the law firm of Cohen Milstein Sellers & Toll PLLC (“Cohen Milstein”) as Lead Counsel, and consolidation of the above-captioned related actions (the “Related Actions”).

The above-captioned action (the “Action”) has been filed against Alkermes; its Chairman and Chief Executive Officer (“CEO”), Richard F. Pops; and its Senior Vice President and Chief Financial Officer (“CFO”), James M. Frates. The Action is predicated on Defendants’ misrepresentation of the Company’s financial condition, and in particular the likelihood of approval of its newest drug to treat depression, and the state of its discussions with the U.S. Food and Drug Administration (“FDA”) about that new drug.

Pursuant to the PSLRA, this Court must appoint the “most adequate plaintiff” to serve as Lead Plaintiff. 15 U.S.C. § 78u-4(a)(3)(B)(i). As such, the Court is required to determine which movant or group of movants has the “largest financial interest” in the relief sought by the Class in this litigation. 15 U.S.C. § 78u-4(a)(3)(B)(iii)(I)(bb). Midwest Operating Engineers’ losses<sup>1</sup>

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<sup>1</sup> Movant’s losses, as detailed herein, are not the same as legally compensable damages, measurement of which is often a complex legal question that generally cannot be determined at this stage of the litigation. The approximate losses can, however, be determined from the executed certification required under Section 21D of the Exchange Act, and based upon reference to

amount to approximately \$2,276,205 during the Class Period as a result of Defendants' conduct. Midwest Operating Engineers is unaware at this time of any other movant with a greater loss. Thus, Midwest Operating Engineers is presumptively the "most adequate plaintiff" and should be appointed as Lead Plaintiff because it has "the largest financial interest in the relief sought by the class." 15 U.S.C. § 78u-4(a)(3)(B)(iii)(I)(bb). Movant is represented in this action by Cohen Milstein, which is seeking appointment as lead counsel and is eminently qualified to prosecute securities class actions such as this one.

## **II. BACKGROUND**

The claims in this case arise from Defendants' alleged misrepresentations and omissions concerning ALKS 5461, its drug for the treatment of Major Depressive Disorder ("MDD"). ALKS 5461 is a once-daily pill premised on the notion that opiates improve mood and therefore might be effective in patients with treatment-resistant MDD. In particular, Defendants' misrepresentations and omissions concern the efficacy of ALKS 5461, the design of the clinical studies the Company used to support its New Drug Application ("NDA") for ALKS 5461, the analyses used to assess the effectiveness of ALKS 5461, and the Company's communications with the FDA regarding ALKS 5461.

Beginning on February 17, 2017 in the Company's 2016 Form 10-K, and throughout the Class Period in SEC filings and other public statements, Defendants represented, *inter alia*, that they were "on track" to begin submission of the NDA; that they were "one step closer to our goal of bringing this important new medicine to patients, families and healthcare professionals"; that the drug "has demonstrated consistent safety, tolerability and antidepressant activity for the

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information concerning the market for Alkermes common stock. *See* Decl. of S. Douglas Bunch in Supp. of Mot. of Midwest Operating Engineers Pension Trust Fund ("Bunch Decl."), at Exs. B and C.

adjunctive treatment of [MDD] throughout its comprehensive clinical development program”; and that the NDA was “based on a comprehensive clinical efficacy and safety package with data from more than 30 clinical trials and more than 1,500 patients with MDD.” Then, on April 2, 2018, the Company announced that it had received a “Refusal to File” letter (“RTF”) from the FDA, and that the FDA had taken the position that it was unable to complete a review of the NDA, citing a need for additional clinical trials and a bioavailability study. In response, Alkermes shares fell from \$57.96 to \$45.32 on April 2 in unusually heavy trading.

Two weeks later, on April 16, Alkermes announced that the FDA had rescinded the RTF and accepted the Company’s NDA for ALKS 5461. Defendants presented this to investors as a “positive step forward,” and indicated that the “issues noted in the RTF will be addressed within the context of the FDA’s review.” Then, on October 30, 2018, the FDA released briefing documents for the November 1, 2018 meeting of the Psychopharmacologic Drugs Advisory Committee (“PDAC”). The briefing documents revealed that the FDA did not agree with Alkermes’ methodologies and, more importantly, that the Company had disregarded the FDA’s explicit advice not to use an abridged version of the diagnostic tool for measuring depressive episodes. Specifically, investors learned, among other things: (1) that the FDA had specifically advised the Company not to use its “abridged” version of the MADRS-10, the accepted diagnostic tool for evaluating the severity of depressive episodes as an endpoint for its clinical studies; (2) that the Company had, against the FDA’s advice, changed the primary endpoint of one of its pivotal Phase 3 studies late in the trial; and (3) that the FDA had objected to the Company’s use of averages of patient scores from different time periods to assess the efficacy of ALKS 5461. Ultimately, the PDAC voted overwhelmingly against approval of ALKS 5461. Trading of Alkermes shares was halted on November 1 and fell from \$40.83 to \$37.74 on November 2 when trading resumed.

### **III. ARGUMENT**

As discussed below, Midwest Operating Engineers satisfies each of the requirements of the PSLRA and is therefore qualified for appointment as Lead Plaintiff. Additionally, Midwest Operating Engineers seeks appointment of Cohen Milstein as Lead Counsel for the Class, and consolidation of the Related Actions.

#### **A. Movant Satisfies the Procedural Requirements for Appointment as Lead Plaintiff**

The Exchange Act, 15 U.S.C. § 78u-4, establishes a procedure for the appointment of a lead plaintiff in “each private action arising under the [Exchange Act] that is brought as a plaintiff class action pursuant to the Federal Rules of Civil Procedure.” 15 U.S.C. § 78u-4(a)(1). First, the plaintiff who files the initial action must publish a notice to the class within 20 days of filing the action, informing class members of their right to file a motion for appointment as lead plaintiff. 15 U.S.C. § 78u-4(a)(3)(A)(i). The first such notice here was published on December 27, 2018 (*see* Bunch Decl., Ex. A).

The PSLRA further provides that within 90 days after the publication of the notice of pendency, or as soon as practicable after the actions have been consolidated, the Court shall consider any motion made by a class member and “shall appoint as lead plaintiff the member or members of the purported plaintiff class that the court determines to be most capable of adequately representing the interests of class members.” 15 U.S.C. § 78u-4(a)(3)(B)(i).

The 60-day time period provided by the PSLRA in which applications for appointment as lead plaintiff must be filed expires on February 25, 2019. Midwest Operating Engineers has moved within the statutory 60-day time period. Its motion contains the required certification setting forth, *inter alia*, its transactions in Alkermes common stock during the Class Period, and indicates that Midwest Operating Engineers has reviewed the complaint filed in the case and is willing to serve

as a representative party on behalf of the Class. *See* Bunch Decl., Ex. B. In addition, Midwest Operating Engineers has selected and retained competent and experienced counsel, as set forth in counsel's resume. *See* Cohen Milstein resume at Bunch Decl., Ex. D. As demonstrated in its resume, Cohen Milstein has developed an excellent reputation for successfully prosecuting federal securities law claims, including in this District and Circuit.

**B. Movant Satisfies the Legal Prerequisites for Appointment as Lead Plaintiff**

**1. Movant Is Presumptively the Most Adequate Plaintiff**

The PSLRA sets forth procedures for the appointment of a lead plaintiff in class actions brought under the Exchange Act. 15 U.S.C. § 78u-4(a)(1). The PSLRA provides that this Court:

shall appoint as lead plaintiff the member or members of the purported plaintiff class that the court determines to be most capable of adequately representing the interests of class members (hereafter in this paragraph referred to as the "most adequate plaintiff") in accordance with this subparagraph.

15 U.S.C. § 78u-4(a)(3)(B)(i). In adjudicating this motion, the Court must be guided by a presumption that the most adequate plaintiff is the person or group of persons who (a) filed the complaint or made a motion to serve as lead plaintiff, (b) has the largest financial interest in the relief sought by the class, and (c) otherwise satisfies the requirements of Fed. R. Civ. P. 23 and 15 U.S.C. § 78u-4(a)(3)(B)(iii)(I). This presumption may be rebutted by proof that the presumptively most adequate plaintiff "will not fairly and adequately protect the interests of the class" or "is subject to unique defenses that render such plaintiff incapable of adequately representing the class." 15 U.S.C. § 78u-4(a)(3)(B)(iii)(II).

Midwest Operating Engineers is qualified for appointment as Lead Plaintiff. During the Class Period, Midwest Operating Engineers suffered losses of approximately \$2,276,205<sup>2</sup> from its

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<sup>2</sup> A copy of Midwest Operating Engineers' certification is attached as Exhibit B to the Bunch Decl. and a copy of its loss calculation is attached as Exhibit C.

purchases of Alkermes common stock. Movant suffered these losses when it was revealed that the Company's financial condition was not as portrayed, and in particular that the status of the FDA's approval of its new drug was not as represented. It is not aware of any other movant with a larger financial interest in the relief sought by the Class.

Because Midwest Operating Engineers believes it possesses the most significant interest in the outcome of this litigation, it is presumed to be the "most adequate" plaintiff. 15 U.S.C. § 78u-4(a)(3)(B)(iii)(I)(bb). Further, Midwest Operating Engineers is both qualified to represent the Class and willing to serve as a representative party. Finally, Midwest Operating Engineers has selected counsel that is highly experienced in prosecuting securities class actions such as this one. Accordingly, Movant satisfies the requirements for appointment as Lead Plaintiff under the PSLRA and its motion for appointment here should be granted.

## **2. Movant Satisfies the Requirements of Rule 23**

In addition to requiring that the lead plaintiff have the largest financial interest, the PSLRA requires that the lead plaintiff must "otherwise satisf[y] the requirements of Rule 23 of the Federal Rules of Civil Procedure." 15 U.S.C. § 78u-4(a)(3)(B)(iii)(I)(cc); *see also In re Elan Corp. Sec. Litig.*, No. 02 Civ. 865 (WK) (FM), 2002 U.S. Dist. LEXIS 23162, at \*7 (S.D.N.Y. Dec. 3, 2002); *Albert Fadem Trust v. Citigroup Inc.*, 239 F. Supp. 2d 344, 347 (S.D.N.Y. 2002). Rule 23(a) requires that (1) the class be so numerous that joinder of all members is impracticable; (2) there be questions of law or fact common to the class; (3) such claims be typical of those of the class; and (4) the representatives fairly and adequately protect the interests of the class. Fed. R. Civ. P. 23(a). Typicality and adequacy of representation are the only provisions relevant to the determination of lead plaintiff under the PSLRA. *In re Symbol Techs., Inc. Sec. Litig.*, No. 05 Civ. 3923, 2006 U.S. Dist. LEXIS 24776, at \*6 (E.D.N.Y. Apr. 26, 2006); *In re Crayfish Co. Sec. Litig.*, No. 00 Civ. 6766 (DAB), 2002 U.S. Dist. LEXIS 10134, at \*14 (S.D.N.Y. June 4, 2002) (citing *In re Olsten*

*Corp. Sec. Litig.*, 3 F. Supp. 2d 286, 296 (E.D.N.Y. 1998) and *Weltz v. Lee*, 199 F.R.D. 129, 133 (S.D.N.Y. 2001)).

The typicality requirement of Fed. R. Civ. P. 23(a)(3) is satisfied where “the claims or defenses of the representative parties are typical of the claims or defenses of the class.” Fed. R. Civ. P. 23(a)(3). A “claim will meet the typicality requirement if ‘each class member’s claim arises from the same course of conduct, and each class member makes similar legal arguments to prove the defendants’ liability.’” *Olstens*, 3 F. Supp. 2d at 296 (quoting *In re Drexel Burnham Lambert Group, Inc.*, 960 F.2d 285, 291 (2d Cir. 1992)); *see also Fields v. Biomatrix, Inc.*, 198 F.R.D. 451, 456 (D.N.J. 2000). The typicality standard is met even where minor distinctions exist. *Id.* As one court has noted: “The premise of the typicality requirement is simply stated: as goes the claim of the named plaintiff, so go the claims of the class. Complete identification between the claims constituting each individual action is not required.” *Chisholm v. TranSouth Fin. Corp.*, 184 F.R.D. 556, 563-64 (E.D. Va. 1999) (internal citation omitted). The typicality requirement is plainly satisfied in the instant case, where Midwest Operating Engineers seeks the same relief and advances the same legal theories as class members.

The adequacy of representation requirement of Rule 23(a)(4) is satisfied where it is established that a representative party “will fairly and adequately protect the interests of the class.” Fed. R. Civ. P. 23(a)(4). Representation is adequate when “(1) class counsel is qualified, experienced and generally able to conduct the litigation; (2) the class members [d]o not have interests that are antagonistic to one another; and (3) the class has a sufficient interest in the outcome of the case to ensure vigorous adequacy.” *Weltz*, 199 F.R.D. at 133 (citing *Olstens*, 3 F. Supp. 2d at 296).

Midwest Operating Engineers is an adequate representative for the class. Movant purchased Alkermes common stock during the Class Period and, like other putative class members,

suffered a loss in the form of diminution of the value of its shares upon disclosure of the fraud. Additionally, Midwest Operating Engineers is a pension fund – precisely the type of institutional investor Congress envisioned serving as lead plaintiff when it enacted the PSLRA. *See H.R. Conf. Rep. No. 104-369*, at 34 (1995) (“The Conference Committee believes that increasing the role of institutional investors … will ultimately benefit shareholders and assist courts by improving the quality of representation in securities class actions.”); *see also In re Gentiva Sec. Litig.*, 281 F.R.D. 108, 113 (E.D.N.Y. 2012) (noting preference among courts for institutional investors). Indeed, Midwest Operating Engineers is a capable, proven fiduciary. Movant is a Taft-Hartley, multiemployer pension fund with assets in excess of \$4.2 billion. Finally, Midwest Operating Engineers has retained counsel highly experienced in prosecuting securities class actions vigorously and efficiently, and has timely submitted its choice to the Court for approval pursuant to 15 U.S.C. § 78u-4(a)(3)(B)(v).

#### **C. The Court Should Appoint Cohen Milstein as Lead Counsel**

The PSLRA vests authority in the lead plaintiff to select lead counsel, subject to approval by the Court. 15 U.S.C. § 78u-4(a)(3)(B)(v). Thus, a court should not disturb the lead plaintiff’s selection of counsel unless such interference is necessary to “protect the interests of the class.” 15 U.S.C. § 78u-4(a)(3)(B)(iii)(II)(aa). Movant has selected Cohen Milstein to serve as Lead Counsel, and appointing Cohen Milstein as Lead Counsel would be prudent to protect the interests of the class.

As detailed in its firm resume, Cohen Milstein has extensive expertise and experience in the field of securities litigation and has successfully prosecuted numerous securities fraud class actions and obtained excellent recoveries on behalf of defrauded investors.<sup>3</sup> Thus, the Court may

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<sup>3</sup> A copy of Cohen Milstein’s firm resume is attached to the Bunch Decl. as Ex. D.

be confident that the class will receive the highest caliber of legal representation in full compliance with the mandates of the PSLRA and Exchange Act. *See* 15 U.S.C. § 78u-4(a)(3)(B)(v); *In re Gilat Satellite Networks, Ltd.*, No. CV-02-1510 (CPS)(SMG), 2007 U.S. Dist. LEXIS 68964, at \*38, 48 (E.D.N.Y. Sept. 18, 2007) (granting final approval to \$20 million settlement in case in which Cohen Milstein served as co-lead counsel, and noting that “Plaintiffs’ Counsel in this case are qualified and experienced in this type of litigation”).

**D. The Related Actions Should Be Consolidated Pursuant to Fed. R. Civ. P. 42(a)**

Class action shareholder suits are ideally suited for consolidation pursuant to Rule 42(a). *See Weltz*, 199 F. R.D. at 131. Indeed, “in securities actions where the complaints are based on the same public statements and reports, consolidation is appropriate if there are common questions of law and fact and the parties will not be prejudiced.” *Weltz*, 199 F.R.D. at 131 (internal quotations and citation omitted).

The Related Actions present virtually identical factual and legal issues and allege the same violations of the federal securities laws. They involve the same parties and arise from the same underlying facts and circumstances. “The proper solution to problems caused by the existence of two or more cases involving the same parties and issues, simultaneously pending in the same court would be to consolidate them under Rule 42(a).” *Hargett v. Valley Fed. Sav. Bank*, 60 F.3d 754, 765-66 (11th Cir. 1995) (quoting *Miller v. United States Postal Serv.*, 729 F.2d 1033, 1036 (5th Cir. 1995)); *see also Internet Law Library, Inc. v. Southridge Capital Mgmt., LLC*, 208 F.R.D. 59, 61 (S.D.N.Y. 2002); *Primavera Familienstiftung v. Askin*, 173 F.R.D. 115, 129 (S.D.N.Y. 1997). Because these actions are based on the same facts and involve the same subject matter, discovery obtained in one lawsuit will undoubtedly be relevant to all others. Consolidation of the Related Actions is thus appropriate as common questions of law and fact predominate in these actions.

Fed. R. Civ. P. 42(a). Thus, consolidation is appropriate here. Accordingly, the motion to consolidate the Related Actions should be granted.

#### **IV. CONCLUSION**

Based on the foregoing, Movant respectfully requests that the Court: (i) appoint Midwest Operating Engineers Pension Trust Fund as Lead Plaintiff; (ii) appoint Cohen Milstein as Lead Counsel; (iii) consolidate the Related Actions; and (iv) grant such other relief as the Court may deem to be just and proper.

Dated: February 25, 2019

Respectfully submitted,

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& TOLL PLLC**

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